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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/259,758 03/01/99 BROWN-SKROBOT

S VTN-0388

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EXAMINER

CHORBAJI, M

ART UNIT

PAPER NUMBER

1744

DATE MAILED:

01/19/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/259,758	Applicant(s) BROWN-SKROBOT ET AL.	
	Examiner MONZER R CHORBAJI	Art Unit 1744	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 March 1999.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-50 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-50 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

Attachment(s)

- | | |
|---|--|
| 15) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 18) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 16) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 19) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 17) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 20) <input type="checkbox"/> Other: |

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a

later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 1-50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Clark et al (U.S.P.N. 5,786,598) in view of Matner et al (U.S.P.N. 5,252,484), and further in view of Shalaby et al (U.S.P.N. 5,422,068), Osipo et al (U.S.P.N. 5,271,874), Dunn et al (U.S.P.N. 4,910,942), and Heyl et al (U.S.P.N. 5,431,879).

Clark et al teaches of a process and an apparatus for sterilizing a medical device, col.1, lines 7-20, comprising the following: medical device, col.1, lines 13-15; ultraviolet radiation, col.3, lines 60-62; in the range of 240-280 nm, col.3, line 3; is exposed at least 3.9 mj/cm², col.8, lines 10-12; sterility assurance level of at least 10⁻⁶, abstract, line 21; at least one pulsed radiation source, col.6, line 26, and col.3, lines 51-56; UV radiation is delivered in less than 1 millisecond, col.8, lines 12-19; radiation sources pulse are pulsed substantially simultaneously, col.10, lines 35-37; reflector, col.6, line 26; radiation is delivered by pulsed radiation source in at most three pulses, col.9, lines 62-67, and col.10, lines 33-37; wherein the fluence of each flash lamp at the focal plane of reflector, figure 1 (22, and 20); wherein medical device is in a container, col.4, lines 55-57; wherein medical device is a contact lens, col.4, lines 55-57; container further

comprises an aqueous solution, col.8, line 4; container further comprises a non-preserved aqueous solution, col.1, lines 10-13; a rare gas as a luminous component, col.10, lines 20-25; more than one radiation source wired in series, figure 1 (22, and the arrows); modifying radiation from a radiation source to eliminate wavelengths which would damage medical device, col.3, lines 33-38; wherein apparatus is light-tight, col.8, lines 37-39; wherein at least one reflector directs radiation from radiation source to a treatment area, figure 1 (18), wherein reflectors have enhanced reflection in the ultraviolet, col.6, lines 42-44; wherein the reflector minimizes the non-ultraviolet radiation reaching the medical device, col.6, lines 45-48; wherein container comprises thermoplastics, col.7, lines 16-21, lines 36-37, and lines 44-47; container is transmissive to radiation in substantially all directions, col.6, lines 45-55; container comprises a lid and a bowl, Clark et al further teaches of applying UV to a medical device to sterilize against spores, col.9, lines 50-53, and provides examples of showing the sterilization effects of UV, or the D-values of spores, columns 10-12 (examples 1-2). In addition; Clark et al teaches of transmissivity of container to UV, col.3, lines 56-62, to be known in the art, col.9, lines 21-32. Furthermore; Clark et al teaches of medical device (contact lens) which blocks (UV-blocker) at least 50 percent of UV, col.4, lines 12-19, and col.8, lines 5-22. Clark et al further teaches that the container and the medical device (contact lens) can be damaged if the proper wave length is not selected, col.3, lines 33-38. In addition; Clark et al teaches of using a power

part of 42

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supply and a capacitance in order to generate radiation within the desired range, col.10, lines 1-8.

Clark et al does not disclose a process and an apparatus for sterilizing a medical device comprising: *Bacillus stearothermophilus* (ATCC 7935), a container with at least 50% transmissivity to UV light, forming contact lens, radiation is produced by a laser, container comprises a lid and a bowl, and hermetically sealed container.

Matner et al teaches of a method for determining the efficacy of a sterilization cycle, col.1, lines 7-8, wherein it is known to use *Bacillus stearothermophilus* (ATCC 7935) to verify how efficient a sterilization cycle is, col.2, lines 35-39.

Matner et al does not teach a method for determining the efficacy of a sterilization cycle comprising: a container with at least 50% transmissivity to UV light, forming contact lens, radiation is produced by a laser, container comprises a lid and a bowl, and hermetically sealed container.

Shalaby et al teaches of methods of sterilization comprising, col.2, lines 20-22; radiation source, col.2, lines 20-48; wherein the concept of D-value is and its importance to sterility assurance level is explained, col.3, lines 28-65; also the D-values of *Bacillus stearothermophilus* are shown, columns 6-11 (examples 1-6). Furthermore; Shalaby teaches of known mathematical relationship between transmissivity, and D-values, col.3, lines 46-57.

Shalaby et al does not teach of methods of sterilization comprising: a container with at least 50% transmissivity to UV light, forming contact lens, radiation is produced by a laser, container comprises a lid and a bowl, and hermetically sealed container.

Osipo et al teaches of a method of forming contact lens, col.1, lines 6-21; and also of hermetically sealed container, col.3, lines 47-48.

Osipo et al does not teach of a method of forming contact lens comprising: a container with at least 50% transmissivity to UV light is used, radiation is produced by a laser, and container comprises a lid and a bowl.

Dunn et al teaches of a method for sterilizing packaging of medical devices, col.1, lines 17-21, wherein a laser is used, col.2, lines 17-22; a container with at least 50% transmissivity to UV light is used, col.6, lines 15-20.

Dunn et al does not teach of a method for sterilizing packaging of medical devices wherein the container comprises a lid and a bowl.

Heyl et al teaches of a method for sterilizing and disinfecting, col.1, lines 11-16, wherein the container comprises a lid and a bowl, col.9, lines 35-37.

Thus, it would have been obvious and one having ordinary skill in the art would have been motivated to combine the teaching of Clark et al for a system and a method of sterilizing a medical device by applying UV radiation to spores with another art-known in the determining the efficacy of sterilization cycles by specifically using *Bacillus stearothermophilus* (ATCC 7935) bacterial spore for

the known and expected results that the bacterial spore is recognized as the most resistant form of bacterial life and further all tests for determining sterilization efficacy use it.

Conclusion

5. The prior art made of record but not relied upon is considered pertinent to applicant's disclosure. Clark et al (U.S.P.N. 5,786,598), Anderson et al (U.S.P.N. 4,528,268), Clark et al (U.S.P.N. 5,925,885), Boucher (U.S.P.N. 3,753,651), Sizer et al (U.S.P.N. 5,843,374), Loshaek et al (U.S.P.N. 5,491,091), and Dunn et al (U.S.P.N. 4,871,559) teach other similar systems and methods sterilizing medical device using UV light.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to MONZER R CHORBAJI whose telephone number is (703) 305-3605. The examiner can normally be reached on M-F 8:30-5:00.

7. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, ROBERT J WARDEN can be reached on (703) 308-2920. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3599 for regular communications and (703) 305-7719 for After Final communications.

8. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0661.

Monzer R. Chorbaji *MR*
Patent Examiner
AU 1744
January 12, 2001

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